UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/759,205	01/16/2001	Richard J. Rovinelli	110346.100US2	3069

24395 7590 01/07/2002

HALE & DORR LLP
THE WILLARD OFFICE BUILDING
1455 PENNSYLVANIA AVE, NW
WASHINGTON, DC 20004

EXAMINER	
GILLIGAN, CHRISTOPHER L	
ART UNIT	PAPER NUMBER
2166	

DATE MAILED: 01/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/759,205	Applicant(s) ROVINELLI ET AL.	
	Examiner Christopher L Gilligan	Art Unit 2166	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-39 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-39 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Response to Amendment

1. In the amendment filed 10/22/01 in paper number 5, the following has occurred: No claims have been amended, canceled, or added. Now claims 1-39 are presented for examination.

2. Applicant's arguments filed 10/22/01 in paper number 5 have been fully considered but they are not deemed to be persuasive.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claims 1-19, 21-26, and 28-39 are rejected under 35 U.S.C. 102(e) as being anticipated by Fink et al, U.S. Patent No. 5,657,255.

5. As per claim 1, Fink et al. teach a computer implemented simulation and evaluation method for simulating interventions including active and passive intervention to a complex system, such as a patient having a set of normal and abnormal conditions such as a health state, by a user, and for evaluating the interventions responsive to predetermined criteria and the interventions, comprising the steps of: accessing the computer implemented simulation and evaluation method by the user (see column 13, lines 31-33); defining a test area to evaluate the user by the computer implemented simulation and evaluation method responsive to at least one of predetermined criteria and a user profile (see column 6, lines 49-56); selecting genetic information of the patient responsive to the test area (see column 6, lines 56-63); generating a

patient history responsive to the test area and the genetic information (see column 6, lines 56-63); receiving at least one intervention input by the user (see column 13, line 18); and evaluating the user responsive to the at least one intervention input by the user and the predetermined criteria (see column 13, lines 18-20).

6. As per claim 2, Fink et al. teach the method of claim 1 as described above, further comprising: evolving the patient responsive to the at least one intervention, the genetic information and the patient history to at least one subsequent health state (see column 13, lines 15-20); and evaluating the user responsive to the at least one intervention input by the user, the at least one subsequent health state, and the predetermined criteria (see column 11, lines 31-35).

7. As per claim 3, Fink et al. teach the method of claim 1 as described above, further comprising the steps of: evolving the patient responsive to the at least one intervention, the genetic information and the patient history to at least one subsequent health state (see column 13, liens 15-20); receiving at least one other intervention input by the user (see column 11, lines 35-36); and evaluating the user responsive to at least one of the at least one intervention input by the user, the at least one other intervention input by the user, the at least one subsequent health state, and the predetermined criteria (see column 11, lines 36-40).

8. As per claim 4, Fink et al. teach the method of claim 1 as described above, further comprising the steps of: evolving the patient responsive to the at least one intervention, the genetic information and the patient history to at least one subsequent health state (see column 13, liens 15-20); receiving at least one other intervention input by the user (see column 11, lines 35-36); evolving the patient responsive to the at least one intervention, the genetic information and the patient history to at least one other subsequent health state (see column 11, lines 36-40); and evaluating the user responsive to at least one of the at least one intervention input by

the user, the at least one other intervention input by the user, the at least one subsequent health state, the at least one other subsequent health state, and the predetermined criteria (see column 11, lines 44-47).

9. As per claim 5, Fink et al. teach the method of claim 1 as described above, wherein said generating step further comprises the step of generating the patient history responsive to the test area, the genetic information, and an entity relationship model (see column 6, lines 56-63).

10. As per claim 6, Fink et al. teach the method of claim 5 as described above, wherein the entity relationship model comprises population, record, agents of change, health states, findings and courses of action (see column 4, lines 20-31).

11. As per claim 7, Fink et al. teach the method of claim 6 as described above, wherein the findings include specific findings, patterns and sub-patterns describing patient behaviors and characteristics (see column 5, lines 16-22).

12. As per claim 8, Fink et al. teach the method of claim 7 as described above, wherein the patterns describe one or more features over time (see column 6, lines 42-46).

13. As per claim 9, Fink et al. teach the method of claim 7 as described above, wherein the sub-patterns describe consequences of patient related events (see column 6, line 66 – column 7, line 6).

14. As per claim 10, Fink et al. teach the method of claim 7 as described above, wherein the patterns model time and characterize interrelated medical observations (see column 4, lines 16-19).

15. As per claim 11, Fink et al. teach the method of claim 7 as described above, fruther comprising the step of performing a differential diagnosis responsive to the findings, the patterns and the sub-patterns (see column 3, lines 4-8).

16. As per claim 12, Fink et al. teach the method of claim 7 as described above, wherein confidence in a presence of the patterns increases with passage of time (see column 9, lines 50-60).

17. As per claim 13, Fink et al. teach the method of claim 6 as described above, wherein the courses of action describe tasks and methods used to apply, modify, and evaluate health state information and characteristics described in the entity relationship model (see column 11, lines 31-35).

18. As per claim 14, Fink et al. teach the method of claim 6 as described above, wherein the courses of action describe patient activities, including at least one of medical and non-medical activities (see column 11, lines 31-35, it is assumed that possible therapies would include medical and non-medical activities).

19. As per claim 15, Fink et al. teach the method of claim 6 as described above, wherein the courses of action describe potential interventions input by the user including at least one of diagnostic and management strategies (see column 3, lines 12-20).

20. As per claim 16, Fink et al. teach the method of claim 6 as described above, wherein the courses of action comprise one or more elementary courses of action used in to construct at least one course of action, one or more types of elementary courses of action corresponding to the one or more elementary courses of action, and weighting factors corresponding to the one or more elementary courses of action (see column 8, lines 25-39).

21. As per claim 17, Fink et al. teach the method of claim 5 as described above, wherein the entity relationship model includes entity relations (see column 5, lines 24-28).

22. As per claim 18, Fink et al. teach the method of claim 17 as described above, further comprising the step of evolving the patient responsive to the at least one intervention, the

genetic information, the entity relations and the patient history to at least one subsequent health state (see column 13, lines 15-20).

23. As per claim 19, Fink et al. teach the method of claim 6 as described above, wherein the entity relationship model includes a health states leads to health states relation describing patient evolution (see column 12, lines 2-4).

24. As per claim 21 Fink et al. teach the method of claim 5 as described above, wherein the entity relationship model links the findings with the patterns to a health state, rather than linking a range of finding values to the health state (see column 11, lines 25-28).

25. As per claim 22, Fink et al. teach the method of claim 6 as described above, wherein the patterns include sensitivity and specificity represented as age dependent rather than as constants (see column 11, lines 28-31).

26. As per claim 23, Fink et al. teach the method of claim 1 as described above, wherein said generating patient history step is executed once for each simulation to generate the patient history used in said computer implemented simulation and evaluation method (see column 6, lines 56-63).

27. As per claim 24, Fink et al. teach the method of claim 2 as described above, further comprising the step of repeating said evolving step, and said receiving step a plurality of times (see column 11, lines 35-40).

28. As per claim 25, Fink et al. teach the method of claim 1 as described above, wherein said generating step generates the patient history comprising a progression of health states and risk factors traversed by the patient from a normal health condition to a specified health condition (see column 13, lines 2-7).

29. As per claim 26, Fink et al. teach the method of claim 1 as described above, wherein said generating step iteratively generates the patient history backwards in time from a specified

health condition to a normal health condition including successive precursor health states and onset times there between (see column 7, lines 36-42).

30. As per claim 28, Fink et al. teach the method of claim 5 as described above, wherein the entity relationship model utilizes tree structures to describe a probability density function conditioned on comorbidities, treatments, risk factors, and the interventions (see column 7, lines 54-67).

31. As per claim 29, Fink et al. teach the method of claim 5 as described above, wherein the entity relationship model includes diagnostic complexities and disease interaction (see column 12, lines 2-4).

32. As per claim 30, Fink et al. teach the method of claim 5 as described above, wherein the entity relationship model includes parallel networks of health states to avoid combinatoric health state explosion (see column 12, lines 4-8).

33. As per claim 31, Fink et al. teach the method of claim 30 as described above, wherein the parallel networks of health states describe at least one of a chronic condition and non-chronic condition (see column 12, lines 19-21, any set of conditions could be linked).

34. As per claim 32, Fink et al. teach the method of claim 30 as described above, wherein the non-chronic condition includes acute exacerbations describing acute flares of illness that occur during a more chronic health condition (see column 12, lines 19-21, any set of conditions could be linked).

35. As per claim 33, Fink et al. teach the method of claim 30 as described above, wherein the parallel networks of health states form at least one of the following interactions: independent interaction between the parallel networks so that patient evolution between first and second parallel networks are unrelated to each other; unilateral interaction between the parallel networks so that patient evolution on a first parallel network is unrelated to the patient evolution

on a second parallel network, and patient evolution on the second parallel network is related to the patient evolution on the first parallel network; and mutually dependent interaction between the parallel networks so that patient evolution between the first and second parallel networks are related to each other (see column 9, lines 42-49).

36. As per claim 34, Fink et al. teach the method of claim 2 as described above, further comprising the stpe of repeating said evolving step to the at least one subsequent health state is responsive to: parallel health states of the patient (see column 12, lines 8-13); and a target health state and health state combinations that lead to different parallel health states (see column 12, lines 22-29).

37. As per claim 35, Fink et al. teach the method of claim 30 as described above, wherein the parallel networks of health states comprise: a primary network including primary health conditions defining a health domain (see column 12, lines 25-27); a risk factor network including risk factors for progression through the primary network (see column 12, lines 27-29); and complications attributed to treating the primary health conditions in the primary network (see column 12, lines 10-13).

38. As per claim 36, Fink et al. teach the method of claim 35 as described above, wherein the parallel networks of health states are generated using the following information: how long at least one of the risk factors exists before influencing a transition between primary health conditions in the primary network (see column 3, lines 15-17); time required for transitions in the primary network, considering different combinations of the risk factors (see column 3, lines 17-20); and number of transitions the patient is allowed to make between a specified health state and a normal health state (see column 13, lines 18-20, it is assumed that the clinical result would include the number of transitions the patient will make).

39. As per claim 37, Fink et al. teach a computer simulation and evaluation system for simulating interventions including active and passive intervention to a patient having a health state by a user, and for evaluating the interventions responsive to predetermined criteria and the interventions, comprising: a knowledge database storing patient health characteristics including at least one of population, record, agents of change, health states, findings and courses of action (see column 4, lines 20-32); a presentation system providing access to the computer implemented simulation and evaluation system by the user (see column 13, lines 31-33); and a patient simulation system adapted to be connectable to said presentation system and said knowledge database, said patient simulation system performing the functions: defining a test area and selecting genetic information of the patient responsive to the test area and the knowledge database (see column 6, lines 49-63); generating a patient history responsive to the test area and the genetic information (see column 6, lines 56-63); receiving at least one intervention input by the user (see column 13, line 18); and evaluating the user responsive to the at least one intervention input by the user and the predetermined criteria (see column 13, lines 18-20).

40. As per claim 38, Fink et al. teach a computer readable tangible medium storing instructions for implementing a process driven by a computer, the process simulating interventions initiated by a user, the interventions including active and passive intervention to a patient having a health state, and the process evaluating the interventions responsive to predetermined criteria and the interventions, the instructions comprising the steps of: accessing the computer implemented simulation and evaluation method by the user (see column 13, lines 31-33); defining a test area to evaluate the user by the computer implemented simulation and evaluation method responsive to at least one of predetermined criteria and a user profile (see column 6, lines 49-56); selecting genetic information of the patient responsive to the test area

(see column 6, lines 56-63); generating a patient history responsive to the test area and the genetic information (see column 6, lines 56-63); receiving at least one intervention input by the user (see column 13, line 18); and evaluating the user responsive to the at least one intervention input by the user and the predetermined criteria (see column 13, lines 18-20).

41. As per claim 39, Fink et al. teach a computer implemented simulation and evaluation method simulates interventions to a patient by a user, and evaluates the interventions responsive to predetermined criteria and the interventions, said method comprising the steps of: defining a test area to evaluate the user by the computer implemented simulation and evaluation method responsive to at least one of predetermined criteria and a user profile (see column 6, lines 49-56); selecting genetic information of the patient responsive to the test area (see column 6, lines 56-63); generating a patient history responsive to the test area and the genetic information (see column 6, lines 56-63); receiving at least one intervention input by the user (see column 13, line 18); and evaluating the user responsive to the at least one intervention input by the user and the predetermined criteria (see column 13, lines 18-20).

Claim Rejections - 35 USC § 103

42. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

43. Claims 20 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fink et al., U.S. Patent No. 5,657,255.

44. As per claim 20, Fink et al. teach the computer implemented simulation and evaluation method according to claim 5 as described above. Fink et al. further teaches relationships

between population, courses of action, agents of change, health states, and findings. Fink et al. do not explicitly teach the entire list of relationships listed in claim 20. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include any one of the specific relationships listed in claim 20. One of ordinary skill in the art would have been motivated to do this for the purpose of observing changes in one entity caused by changes in another.

45. As per claim 27, Fink et al. teach the computer implemented simulation and evaluation method according to claim 1 as described above. Fink et al. do not explicitly teach using a Monte Carlo process to multiple stochastic trees to generate a plurality of potential patient histories to be used in said computer implemented simulation and evaluation method. However, Monte Carlo process is old and well known in the art of statistical analysis. It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply a Monte Carlo process to generate a plurality of potential patient histories for use in the simulation and evaluation method of Fink et al. for the purpose of comparing multiple patient histories for the same patient.

Response to Arguments

46. In the remarks filed 10/22/01 in paper number 5, Applicants argue in substance that (1) Fink et al. does not teach generating a patient history; (2) Fink et al. does not teach evaluating the user in response to at least one intervention input by the user and predetermined criteria; (3) the specific features of claim 27 are not well known.

47. In response to Applicants' argument (1), Fink et al. teaches tracing a biological variation back to a specific genetic variation. This is taken to be equivalent to generating a patient history from selected genetic information.

48. In response to Applicants' argument (2), column 13, lines 18-20 clearly teach this limitation. In this passage, Fink et al. describes inputting a drug or treatment regimen and outputting a result from applying the treatment to the patient.

49. In response to Applicants' argument (3), Examiner maintains that Monte Carlo process is old and well known as evidenced by the Concato and Feinstein article. Furthermore, Fink et al. teaches running the simulation multiple times to produce variations in clinical responses (see column 9, lines 31-33. Therefore the rejection is proper.

Conclusion

50. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

51. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

52. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Luke Gilligan whose telephone number is (703) 308-6104. The examiner can normally be reached on 8am-5:30pm.

53. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tariq R Hafiz can be reached on (703) 305-9643. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 746-5579 for regular communications and (703) 308-1396 for After Final communications.

54. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3900.

CLG
January 2, 2002

TARIQ R. HAFIZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 2100